

AQUABEAM SCOPE

Reprocessing Instructions – (US)



PROCEPT BioRobotics
900 Island Drive, Suite 201
Redwood City, CA 94065
United States
Tel: +1 (650) 232-7222
Fax: +1 (888) 285-3777

Email:
cs@PROCEPT-BioRobotics.com
Web:
www.PROCEPT-BioRobotics.com



PART 1: GENERAL INFORMATION AND PRECAUTIONS

1.1 - INTRODUCTION

These instructions contain the cleaning and sterilization methods recommended by PROCEPT BioRobotics for the AQUABEAM Scope (REF 210501). These instructions contain essential information on reprocessing this Scope safely and effectively.

Before reprocessing, thoroughly review the manuals of the reprocessing chemicals and all equipment which will be used. Reprocess the Scope as instructed.

Keep these instructions and all related manuals in a safe and accessible location.

If you have any questions or comments about any information in these instructions, or if a problem that cannot be solved occurs while reprocessing, contact PROCEPT BioRobotics.

1.2 - IMPORTANCE OF CLEANING AND STERILIZATION

The medical literature reports incidents of cross contamination resulting from improper cleaning or sterilization. It is strongly recommended that all individuals engaged in reprocessing closely observe all instructions given here and the manuals of all ancillary equipment, and have a thorough understanding of the following items:

- Professional health and safety criteria of your hospital
- Individual cleaning and sterilization protocols
- Structure and handling of cystoscopic equipment
- Handling of pertinent chemicals
- Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings (US CDC)

1.3 - SIGNAL WORDS

The following signal words are used throughout these instructions:

WARNING Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential Scope damage.

NOTE Indicates additional helpful information

1.4 - GENERAL PRECAUTIONS

WARNING

- This device is supplied non-sterile. Failure to properly clean and sterilize the Scope initially and after each procedure may compromise device performance and sterility.
- Initially and after each procedure the Scope and its ancillary equipment must undergo thorough manual cleaning followed by sterilization as described in these instructions.

- If the Scope is not cleaned properly, effective sterilization may not be possible. Clean the Scope thoroughly before sterilization to remove microorganisms or organic material that could reduce the efficacy of sterilization.
- Patient debris and reprocessing chemicals are hazardous. Wear personal protective equipment to guard against dangerous chemicals. Always remove contaminated personal protective equipment before leaving the reprocessing area.
- Thoroughly rinse off the cleaning solution. Rinse the external surface of the Scope and the cleaning equipment thoroughly with water to remove any cleaning solution residue.
- The sterilization room must be adequately ventilated. Adequate ventilation protects against the buildup of toxic chemical fumes.
- Store alcohol in an air-tight container. Alcohol stored in an open container is a fire hazard and will result in a loss of efficacy due to evaporation.
- Prior to each procedure, confirm that the Scope has undergone proper cleaning and sterilization. If it is determined that the Scope has not been properly reprocessed, do not use and reprocess it again following the Scope Cleaning instructions given here.
- With the cleaning and sterilization methods stated in these instructions, prions, which are considered, to be the pathogenic substance of the Creutzfeldt-Jakob disease (CJD) cannot be destroyed or inactivated. When using this Scope on a patient with CJD or variant Creutzfeldt-Jakob disease (vCJD), be sure to use this Scope for such patient only and/or immediately dispose of this Scope after use in an appropriate manner. For methods to handle CJD, please follow the respective guidelines in your country.
- If cleaning methods other than those stated in document are performed (such as the respective methods stated in the guidelines of each country for destroying or inactivating prions), PROCEPT BioRobotics cannot guarantee the effectiveness, safety, and durability of this Scope. Make sure to confirm that there is no abnormality before use, and use under responsibility of a physician. Do not use if any abnormality is found.

CAUTION

- After using this Scope, reprocess and store it according to the instructions given in this document. Improper and/or incomplete reprocessing or storage can present an infection control risk, cause Scope damage or reduce performance.
- If the Scope is not immediately cleaned after each procedure, residual organic debris will begin to solidify, and it may be difficult to effectively reprocess the Scope.
- These Scopes are not compatible with steam sterilization or Plasma, which may cause damage to the Scope.
- A thorough, manual cleaning and sterilization process is recommended. The Scope should be cleaned and sterilized by following the manual cleaning and sterilization procedures contained in this document.
- Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used.
- It is the responsibility of the reprocessor to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained in order to achieve the desired result. Any deviation by the reprocessor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

1.5 - REPROCESSING BEFORE THE FIRST USE / REPROCESSING AND STORAGE AFTER USE

This Scope was not cleaned, disinfected or sterilized before shipment. Before using the Scope for the first time, reprocess it according to these instructions.

After using the Scope, reprocess and store it according to these instructions. Improper and/or incomplete reprocessing or storage can present an infection control risk, cause Scope damage or compromise device performance.

PART 2: COMPATIBLE CLEANING CHEMICAL AGENTS/SOLUTIONS AND STERILIZATION METHOD

2.1 - COMPATIBILITY SUMMARY

The AQUABEAM SCOPE is compatible with only the cleaning chemical agents/solutions and sterilization method methods listed in Table 2.1.

CAUTION: Any cleaning chemical/solutions and sterilization methods that are not listed in Table 2.1 can cause Scope damage.

Table 2.1 Compatible Cleaning Chemical Agents/Solutions and Sterilization Method

Liquid Dish Soap Solution
Enzol [®] Solution or equivalent enzymatic detergent
70% ethyl or isopropyl alcohol
Ethylene-Oxide Sterilization
STERRAD NX (Standard Cycle)
STERRAD 100S
STERIS V-Pro (Non-Lumen Cycle)
STERIS SYSTEM 1E Liquid Chemical Sterilant (Standard Cycle)

WARNING Liquid Soap and Alcohol are not a sterilant, and should only be used as a precursor to or after sterilization (See sections 2.4 and 3.6).

2.2 - LIQUID DISH SOAP SOLUTION

Use a commercially-available liquid dish soap such as Ivory[®] and follow the recommended dilution ratio of ~1mL/4L (¼tsp/Gal) of warm tap water. Do not reuse detergent solutions. This is important for removing non-water-based lubricants that may be used in PROCEPT BioRobotics procedures.

2.3 - DETERGENT SOLUTION

Use a medical-grade, low-foaming, neutral pH detergent or enzymatic detergent such as Enzol[®] and follow the manufacturer's dilution and temperature recommendations. Do not reuse detergent solutions.

2.4 - RINSING WATER

Once removed from cleaning solution, the Scope must be thoroughly rinsed with sterile water to remove any cleaning residue. If sterile water is not available, clean potable tap water or water which has been processed (e.g., filtered) to improve its microbiological quality may be used.

When non-sterile water is used after cleaning, wipe the Scope with 70% ethyl or isopropyl alcohol, then air-dry to inhibit the growth of residual bacteria. Do not reuse rinsing water.

PART 3: CLEANING PROCEDURES

CAUTION

- For transport and temporary storage, do not coil the Scope flexible (black) section with a diameter of less than 10cm (4in). The Scope can be damaged if coiled too tightly.
- The stainless steel section of the Scope is not flexible. Do not coil the stainless steel section.

3.1 - REQUIRED REPROCESSING EQUIPMENT

The following commercially available brushes and tools are recommended for use when reprocessing the AQUABEAM Scope:

Olympus Cleaning brush MH-507 or equivalent.

3.2 - CLEANING AND STERILIZATION PROCEDURES

Clean and sterilize the Scope according to the procedure described below.

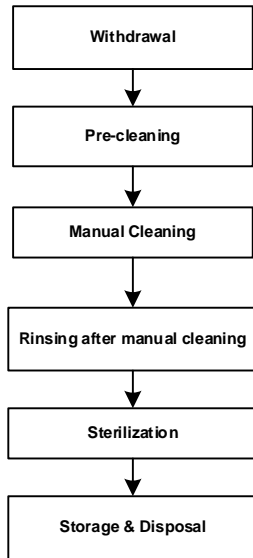


Figure 3.1 - Reprocessing Overview

3.3 – DISASSEMBLY AND PRE-CLEANING

Disassemble and wipe down the exterior of the Scope immediately after each procedure by following the instructions below. Then, immediately pre-clean the Scope by thoroughly brushing and rinsing per the steps below. Wear appropriate personal protective equipment during pre-cleaning and observe Universal Precautions for the Prevention of Transmission of Bloodborne Pathogens in the Healthcare Setting.

Equipment Needed

- **Personal Protective Equipment**
- **Large Basins**
- **Liquid Dish Soap Solution**
- **Clean Tap Water**
- **Short Brushes (Olympus Model MH-507 or equivalent)**

[Scope Disassembly]

1. Remove the light adapter from the Scope. The light adapter is to be reprocessed in the same manner as the Scope.

[Scope Preparation]

2. Wipe down the external surfaces of the Scope with a damp cloth to remove excess debris. Keep the Scope moist and do not allow the Scope and debris to dry completely prior to pre-cleaning.

[Pre-Cleaning Preparation]

3. Prepare a large container of liquid dish soap solution at a concentration of ~1mL/4L of warm tap water.
4. Prepare clean tap water in a large container.

[Brush down the Scope]

WARNING Handle the Scope carefully. Tightly gripping or sharply bending the Scope section can stretch or damage the Scope.

5. Fully immerse the Scope in the dish soap solution. Brush down the entire the Scope with a soft-bristled brush and liquid dish soap solution. Ensure all hard-to-reach areas are accessed.
6. Rinse the Scope with clean tap water for at least 1 minute to remove all detergent residues.

3.4 - MANUAL CLEANING

Equipment Needed

- **Personal Protective Equipment**
- **Large Basins**
- **Soft bristle brush or equivalent**
- **Detergent solution - Enzo[®] Solution**
- **Clean Water**

1. Prepare a basin of detergent solution at the temperature and concentration recommended by the detergent manufacturer. The basin must be deep enough to allow the Scope to be completely immersed.
2. Prepare a second basin of clean water. The basin must be deep enough to allow the Scope to be completely immersed.

3. Completely submerge the Scope in the detergent solution. Allow Scope to soak for a minimum of 10 minutes.
4. With the Scope immersed, use a soft-bristled brush to thoroughly brush or wipe all external surfaces of the Scope. Particular attention shall be given to crevices, mated surfaces and other hard-to-clean areas until all visible soil has been removed.

NOTE The detergent solution should be changed if it becomes contaminated (bloody and/or turbid).

5. Remove the Scope from the detergent solution and rinse in clean water for a minimum of 1 minute -- or longer if needed -- until there is no sign of blood or soil in the rinse stream. Thoroughly flush difficult to reach areas.
6. Dry the Scope with a clean soft cloth or disposable, absorbent, non-shedding wipe.
7. Filtered, pressurized air (not to exceed 48kPa (7psi)) may be used to assist drying.
8. Inspect the Scope for residual debris. Should debris remain, repeat the manual cleaning procedure.

3.5 - RINSING AFTER MANUAL CLEANING

Equipment Needed

- **Personal Protective Equipment**
- **Large Basin**
- **Clean Lint-Free Cloths**
- **Sterile Water**
- **70% IPA**

1. Fill a basin with USP grade sterile water. The basin must be deep enough to allow the Scope to be completely immersed.
2. Immerse the Scope in the sterile water for a minimum of 1 minute.
3. Discard the rinse water.
4. Refill the basin with USP grade sterile water.
5. Re-immers the Scope in sterile water for a minimum of 1 minute.
6. Using a sterile, lint-free cloth, thoroughly dry all external surfaces.
7. Wipe all external surfaces with 70% isopropyl alcohol (IPA).
8. Using a sterile, lint-free cloth, thoroughly wipe and dry all external surfaces.

3.6 –STERILIZATION

WARNING

- **Before sterilization, the Scope must be thoroughly cleaned and all visible organic material, blood and cleaning solution completely removed.**
- **The approved sterilization parameters are only valid with sterilization equipment that is properly maintained and calibrated.**
- **Any deviations from the recommended parameters for sterilization should be validated by the user.**

3.6.1 EtO Sterilization

1. Place the Scope in a sterilization tray.
2. Wrap with two layers of EtO compatible polypropylene wrap or equivalent material, or seal in a Tyvek pouch intended for EtO sterilization.
3. PROCEPT BioRobotics has validated Ethylene Oxide (EtO) sterilization using the following parameters:

Conditioning Parameters (In-Chamber)

Temperature (set point): 55°C (131°F)
 Humidity: ≥ 70% RH
 Vacuum (set point): 1.3 psia
 Conditioning Dwell Time: 30 minutes

Sterilization Parameters

Sterilant: 100% Ethylene Oxide
 Temperature (set point): 55°C (131°F)
 Humidity: ≥ 70% RH
 Humidity Dwell Time: 30-45 minutes
 EO Gas Concentration: 725 ± 30 mg/L
 EO Gas Exposure Time: 120 minutes

Aeration Parameters

Time: 12 hours
 Temperature (set point): 55°C (131°F)

Temperature range: 51° - 59°C (124° - 138°F)

3.6.2 STERRAD 100S

Use standard cycle for sterilization.

Follow the manufacturer's instructions for using the STERRAD 100S system.

3.6.3 STERRAD NX

Use standard cycle for sterilization.

Follow the manufacturer's instructions for using the STERRAD NX system.

3.6.4 STERIS V-Pro 1 Plus, V-Pro maX

Use non-lumen cycle for sterilization

Follow the manufacturer's instructions for using the STERIS V-Pro 1 Plus and V-Pro maX

3.6.5 STERIS SYSTEM 1E Liquid Chemical Sterilant

Use standard cycle for sterilization

Follow the manufacturer's instructions for using the STERIS SYSTEM 1E Liquid Chemical Sterilant

3.7 - INSPECTION & FUNCTION TESTING PRIOR TO USE

1. Carefully inspect each Scope to ensure that all visible blood and soil has been removed.
2. Visually inspect for damage and/or wear.
 - Discontinue use of the Scope if any part appears cracked, slit or otherwise damaged along its length or joints of surfaces.
 - Discontinue use of the Scope if any of the distal stainless steel sections of the Scope exhibit pitting, corrosion or other visual defects.
 - Discontinue use of the Scope if image quality degrades below acceptable limit as determined by the user (physician)
3. Notify PROCEPT BioRobotics of any Scopes removed from service for further evaluation.

PART 4: STORAGE AND DISPOSAL

4.1 - STORAGE OF REUSABLE PARTS AND REPROCESSING SCOPE

Clean, sterilized, reprocessed Scopes should be stored in a designated, limited access area that is well ventilated and provides protection from contaminated equipment, dust, moisture, insects, vermin, and temperature/humidity extremes.

Do not store the Scope in direct sunlight, at high temperature, in high humidity or exposed to x-rays and ultraviolet rays. These could damage the Scope or pose an infection-control risk.

Do not store the Scope in a cystoscope carrying case. Routinely storing the Scope in a humid, non-ventilated environment, such as the carrying case, may present an infection control risk. If such storage is required, ensure the Scope is properly reprocessed after removal from storage case and subsequent use.

This document may not be altered in any way without prior consent of PROCEPT BioRobotics. Unauthorized reproduction, distribution, or use of this document, or any portion thereof, is strictly prohibited and may result in severe civil and criminal penalties.

Copyright ©2018 by PROCEPT BioRobotics. All Rights Reserved AQUABEAM is a registered trademark of AQUABEAM.